

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	tba	Art Unit:	1615
Filed:	tba	Examiner:	S. Tran
1 st Inventor:	SHIMIZU, T.	Allowed:	
For:	Orally Disintegrable Tablets	Batch:	
Atty. Dkt. No.	2522 US2P	Paper No.:	

PRELIMINARY AMENDMENT

Box NEW APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT

In the Specification

Please insert on Page 1 as the first sentence of the application the following:

-- This application is a continuation of U.S. Patent Application
Serial No. 09/355,781, now U.S. Patent No. _____,
issued _____, which was the National Phase filing of
International Patent Application No. PCT/JP99/02548, filed May
17, 1999. --

In the Claims

Please substitute the following Claim 1 as Amended for Claim 1.

Please substitute the following Claim 32 as Amended for Claim 32.

Please cancel Claims 10 and 37 without prejudice to filing future continuing applications.

1999

[illegible]

32. (AMENDED) Fine granules having an average particle diameter of 400 μm or less, which comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having (i) 25 weight % or more of an acid-labile physiologically active substance and (ii) a basic inorganic salt.

Mark-up of Amendment to Claims

1. (AMENDED) An orally disintegrable tablet which comprises

- (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having 10 weight % or more of an acid-labile physiologically active substance and
- (ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg is orally disintegrable.

10. (Canceled)

32. (AMENDED) Fine granules having an average particle diameter of 400 μm or less, which comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained release agent, said composition having (i) 25 weight % or more of an acid-labile physiologically active substance and (ii) a basic inorganic salt.

37. (Canceled)

REMARKS

I. Amendments

Reference to Prior applications is inserted into the specification by this amendment.

Claim 1 has been amended to recite that the tablet has a hardness strength of about 1 kg to about 20 kg and is orally disintegrable. Support for this amendment is found in the specification and claims as filed (for example, on page 23, lines 9-11).

Claims 1 and 32 have been amended to further clarify the composition of the claimed invention as having an enteric coating layer "comprising a first component which is an enteric coating agent and a second component which is a sustained release agent."

Claims 10 and 37 have been canceled without prejudice.

II. Conclusion

Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, she is respectfully requested to call applicants' attorney at (847) 383-3372.

Respectfully submitted,

Dated: October ³⁰~~25~~, 2001

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